510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k042406

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator for Lactic Acid (Lactate)

D. Type of Test:

Quantitative Immunoassay

E. Applicant:

Olympus America, Inc.

F. Proprietary and Established Names:

Olympus Lactate Calibrator

G. Regulatory Information:

1. Regulation section:

   21 CFR § 862.1150 (Calibrator)

2. Classification:

   Class II

3. Product code:

   JIT

4. Panel:

   75 Clinical Chemistry

H. Intended Use:

1. Intended use / Indication(s) for use:

   The Olympus lactate calibrator is a device intended for medical purposes for use in the Olympus lactate test system to establish a standardized point of reference that is used in the determination of lactate values in human plasma and cerebrospinal fluid.

2. Special conditions for use statement(s):

   Prescription use only

3. Special instrument requirements:

   Olympus AU family of analyzers only

I. Device Description:

The Olympus Lactate Calibrator contains L-Lactate and comes in ready-to-use liquid form in a 5 mL bottle. It is a single-level calibrator designed for use with Olympus analyzers only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Casco Standards Document Ammonia/Ethanol/Lactate Calibrator

2. Predicate 510(k) number(s):

   k81436

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Preparation	Same	Liquid, ready to use
Storage	Same	2 - 8 °C

Differences		
Item	Device	Predicate
Analytes	Lactate Only	Ammonia, Ethanol, Lactate
Number of Levels	One	Two
Number of Applicable Analyzers	Olympus AU family only	Multiple Analyzers

K. Standard/Guidance Document Referenced (if applicable):

None Referenced

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable.

b. Linearity/assay reportable range:

Not Applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability. The sponsor states that the calibrator is traceable to a primary internal standard obtained from weighed purified material.

Shelf-life Stability. Shelf-life stability was established by calibrating the assay and analyzing controls in real time. Acceptance criteria were as follows: low control ≤ 10% CV, medium control ≤ 7% CV, and high control ≤ 5% CV. All criteria were met at 36 months; however, the sponsor has chosen to use 24 months as the shelf-life stability.

Opened Bottle Stability. To assess opened bottle stability, the sponsor analyzed the calibrator as an unknown in triplicate at day 0, day 60, and day 120 (storage at 4^{o} C). The sponsor's acceptance criteria were that the mean of the measurements must be ≤ 3% difference from the assigned value. The mean of the measured values met the sponsor's acceptance criteria at day 120,

establishing the opened bottle stability claim of 120 days as specified in the labeling.

Value Assignment. For value assignment, the assay is calibrated with a primary standard using previously released lots of lactate reagent. Included in the value assignment run are two levels of control (for validation of the run), a secondary standard (to check the commutability of the standard), a primary standard (for supplemental run validation), a previous lot standard (to check the lot consistency), and 10 replicates of the calibrator lot to which a value is being assigned. If all control and standard values fall within range, the ten replicates of the new calibrator lot are averaged and the mean is assigned as the value.

d. Detection limit:

Not Applicable.

e. Analytical specificity:

Not Applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable.

b. Matrix comparison:

Not Applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:**

   Not Applicable.

5. Expected values/Reference range:

   Not Applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.